510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	22-December-2010
Submitter:	GE Healthcare, (GE Healthcare Finland Oy) Kuortaneenkatu 2 FIN-00510 Helsinki, Finland
Primary Contact Person:	Tommi Jokiniemi RA Leader GE Healthcare, (GE Healthcare Finland Oy) Tel +358-10-394 6561 fax +358-9-2726532
Secondary Contact Person:	Tatja Pasanen RA Leader GE Healthcare, (GE Healthcare Finland Oy) Tel +358-10-394 2243 fax +358-9-2726532
Device: Trade Name:	TruSignal® SpO2 PediTip Sensor
Common/Usual Name:	Pulse Oximeter Sensors
Classification Names:	21CFR870.2700
Product Code:	DQA
Predicate Device(s):	K101871 TruSignal® SpO2 FingerTip Sensors K882609 Philips M1192A Reusable SpO2 sensor
Device Description:	Pulse oximeter sensors connecting to patient monitors
Intended Use:	TS-SP3-GE *The sensor is a reusable sensor intended for use for continuous non-invasive arterial oxygen saturation (SpO2) and pulse rate monitoring. Patient weight range: 15-30 kg (33-66 pounds)* TS-SP3-MC *The sensor is a reusable sensor intended for use for continuous non-invasive arterial oxygen saturation (SpO2) and pulse rate monitoring. Patient weight range: 15-30 kg (33-66 pounds)* TS-SP-D *The sensor is a reusable sensor intended for use for continuous*

non-invasive arterial oxygen saturation (SpO2) and pulse rate monitoring. Patient weight range: 15-30 kg (33-66 pounds)

Technology: The TruSignal® SpO2 PediTip Sensors employ the same fundamental scientific technology as its predicate devices. They are identical to the predicate device TruSignal® SpO2 FingerTip Sensors except for the sensor head geometry. All optical and electrical components of the sensors are identical to the predicate device TruSignal® SpO2 FingerTip Sensors.

To demonstrate sensor geometry did not have an adverse effect on the performance of the products, the products were tested for safety, mechanical durability, electromagnetic compatibility, current transfer ratio and crosstalk. As the proposed devices performed equal or better in all of these areas, the performance of the proposed device is at least equal to the predicate device TruSignal® SpO2 FingerTip Sensors.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The TruSignal® SpO2 PediTip Sensors and their applications comply with voluntary standards as detailed in Section 9 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, TruSignal® SpO2 PediTip Sensors, did not require clinical studies to support substantial equivalence.

This sensor has identical materials and electro-optical components and equivalent sensor characteristics, thus the clinical data from TruSignal FingerTip SpO2 Sensor K101871 applies to this sensor as well.

Conclusion: GE Healthcare considers the TruSignal® SpO2 PediTip Sensors to be as safe, as effective, and performance is substantially equivalent to the predicate device TruSignal® SpO2 FingerTip Sensors.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Tatja Pasanen
Regulatory Affairs Leader
GE Healthcare Finland OY
Kuortaneekatu 2
FIN-00510 Helsinki, Finland

AUG - 2 2011

Re: K103802
Trade/Device Name: TruSignal® SpO2 PediTip Sensors
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: July 25, 2011
Received: July 27, 2011

Dear Ms. Pasanen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/ CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem /default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: TruSignal® SpO2 PediTip Sensors

Indications for Use:

TS-SP3-GE
The sensor is a reusable sensor intended for use for continuous non-invasive arterial oxygen saturation (SpO2) and pulse rate monitoring. Patient weight range: 15-30 kg (33-66 pounds)

TS-SP3-MC
The sensor is a reusable sensor intended for use for continuous non-invasive arterial oxygen saturation (SpO2) and pulse rate monitoring. Patient weight range: 15-30 kg (33-66 pounds)

TS-SP-D
The sensor is a reusable sensor intended for use for continuous non-invasive arterial oxygen saturation (SpO2) and pulse rate monitoring. Patient weight range: 15-30 kg (33-66 pounds)

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultz

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K103802